# *Coding and Billing for ALYGLO® (immune globulin intravenous, human-stwk), 10% Liquid*

Alyglo®
immune globulin intravenous, human-stwk 10% liquid

## *Permanent HCPCS code for ALYGLO®, J1552 Injection, immune globulin (Alyglo), 500 mg active for dates of service on and after January 1, 2025*

### Disclaimer

GC Biopharma USA, Inc. developed this document to support healthcare providers (HCPs) in coding for ALYGLO through specialty pharmacies and the home. This document provides guidance for the Food and Drug Administration (FDA) approved indications that are documented in the ALYGLO Prescribing Information. The content in this document is provided for informational purposes only. This information is not legal advice, and it does not guarantee reimbursement for any product or service. Payer guidance changes frequently and varies by health insurance plan. HCPs should ensure that information reported to payers accurately reflects the services that were rendered and documented in the patient's medical record.

### ALYGLO Support

Contact the ALYGLO Support Team at (888) 501-8040 or visit https://alyglo.medmonk.com/patient_support for help with navigating your patient's insurance coverage, determining copay eligibility, and other reimbursement support as needed.

### Indication[1]

ALYGLO® is indicated for the treatment of primary humoral immunodeficiency (PI) in adults aged 17 years and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency (CVID), Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

### Important Safety Information

**WARNING: THROMBOSIS, RENAL DYSFUNCTION and ACUTE RENAL FAILURE**

**Thrombosis may occur with immune globulin intravenous (IGIV) products, including ALYGLO. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**

**Renal dysfunction, acute renal failure, osmotic nephropathy, and death may occur with the administration of IGIV products in predisposed patients.**

**Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. ALYGLO does not contain sucrose.**

**For patients at risk of thrombosis, renal dysfunction or renal failure, administer ALYGLO at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

**Contraindications:** ALYGLO is contraindicated in patients who have a history of anaphylactic or severe systemic reaction to the administration of human immune globulin and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

**Please see Important Safety Information throughout and Full Prescribing Information, including BOXED WARNING.**

## Coding and Billing for ALYGLO

The codes provided below may be used to report a healthcare encounter for a patient receiving ALYGLO. Medical record documentation must support the codes reported on claims. Individual payer policies should be verified for additional reporting requirements.

## International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM)

ICD-10-CM codes are used in all sites of care to support the diagnosis and medical necessity of treatment with ALYGLO. ALYGLO is indicated for treatment of primary humoral immunodeficiency in adults. Other codes may apply; coverage may also vary by payer. Final codes must be supported by the HCP's medical record documentation.

| ICD-10-CM Code[2] | Description |
|---|---|
| D80.0 | Hereditary hypogammaglobulinemia |
| D80.5 | Immunodeficiency with increased immunoglobulin M [IgM] |
| D81.1 | Severe combined immunodeficiency [SCID] with low T- and B-cell numbers |
| D82.0 | Wiskott-Aldrich syndrome |
| D83.9 | Common variable immunodeficiency, unspecified |

## Healthcare Common Procedure Coding System (HCPCS)

A product-specific code for ALYGLO is active for dates of service on and after January 1, 2025.

| HCPCS Code[3] | Description | Appropriate use |
|---|---|---|
| J1552 | Injection, immune globulin (Alyglo), 500 mg | Report 1 billing unit of J1552 per 500 mg; 1000 mg = 1 gram (g) = 2 billing units. Similarly, on the claim form:<br>• 5 g are reported with 10 billing units<br>• 10 g are reported with 20 billing units<br>• 20 g are reported with 40 billing units |

## Modifiers

HCPCS modifiers may be used on applicable ALYGLO claims to provide additional information.

| Modifier[3,4] | Description | Appropriate use |
|---|---|---|
| JW | Drug amount discarded/not administered to any patient | Report modifier JZ with J1552 when all of the drug in the single-use vial was administered. |
| JZ | Zero drug amount discarded/not administered to any patient | Report modifier JW with J1552 for any amount of discarded drug on a separate claim line from the amount of drug that was administered. |
| SS | Home infusion services provided in the infusion suite of the intravenous (IV) therapy provider | These modifiers may be reported to indicate the administration was provided by a home infusion provider/specialty pharmacy within the 4 walls of an infusion center vs in a patient's home and/or by a registered nurse. These informational modifiers do not impact payment. Review payer policies for reporting requirements. |
| SD | Services provided by registered nurse with specialized, highly technical home infusion training | |

## ALYGLO National Drug Code (NDC)

The correct 11-digit National Drug Code (NDC) without hyphens must be reported on claims. The NDC is typically preceded with NDC qualifier "N4". When required by payers, report "ML" as the unit of measure and NDC quantity.[5] Check payer reporting requirements.

| Vial NDC | Carton NDC | 11-digit Billing NDC | Description |
|---|---|---|---|
| 61476 -104-01 | **61476-104-05** | 61476-**0**104-05 | One 5 g single-dose vial in 50 mL |
| 61476 -104-02 | **61476-104-10** | 61476-**0**104-10 | One 10 g single-dose vial in 100 mL |
| 61476 -104-03 | **61476-104-20** | 61476-**0**104-20 | One 20 g single-dose vial in 200 mL |

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## Administration

The following codes may be used to report the intravenous infusion of ALYGLO. Check payer reporting requirements for appropriate reporting for home infusion services.

| Current Procedural Terminology (CPT)/ HCPCS Code[3,6] | Description | Appropriate use |
|---|---|---|
| 96365 | IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour | CPT code 96365 is used to report an IV infusion lasting up to 90 minutes.<br><br>CPT code 96366 should be reported in addition to 96365 when the IV infusion lasts at least 91 minutes. |
| 96366 | IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure) | |
| 99601* | Home infusion/specialty drug administration, per visit (up to 2 hours) | |
| 99602* | Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (list separately in addition to code for primary procedure) | |
| S9338* | Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem | |
| Q2052 | Services, supplies, and accessories used in the home for the administration of intravenous immune globulin (IVIG) | A bundled payment is provided to durable medical equipment (DME) suppliers under Medicare Part B for nursing services, items, and services that are necessary for the in-home administration of IVIG.[7] |

*Not payable by Medicare for home infusion

## Coverage Overview statement for ALYGLO

Medicare, Medicaid, and most insurers cover ALYGLO for the treatment of patients with primary humoral immunodeficiency. ALYGLO, services, and supplies are covered under various Medicare benefits depending on the site of care. Medicaid and commercial coverage policies vary by state and contracts, respectively.

**Please see Important Safety Information throughout and Full Prescribing Information, including BOXED WARNING.**

## References

**1.** ALYGLO. Prescribing information. GC Biopharma USA, Inc.; 2023. **2.** CMS. 2025 ICD-10-CM code tables, tabular, and index. Accessed January 21, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes **3.** CMS. HCPCS January 2025 alpha-numeric file. Accessed January 21, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **4.** CMS. Medicare program: discarded drugs and biologicals – JW modifier and JZ modifier policy. Accessed January 21, 2025. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **5.** CMS. Medicare claims processing manual: Chapter 26 - completing and processing form CMS-1500 data set. Updated June 6, 2024. Accessed January 21, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf **6.** AMA. 2025 CPT professional edition. Current Procedural Terminology (CPT®) copyright 2024 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. AMA; 2024. **7.** CMS Manual System. Transmittal 12437: implementation of the new home intravenous immune globulin (IVIG) items and services payment. Accessed January 21, 2025. https://www.cms.gov/files/document/r12437cp.pdf#page=10


## Important Safety Information, cont.

**Hypersensitivity:** In case of hypersensitivity, discontinue infusion immediately and institute appropriate treatment. Epinephrine should be available for immediate treatment of severe acute hypersensitivity reactions.

**Hyperproteinemia, Increased Serum Viscosity, and Hyponatremia**: Hyperproteinemia, increased serum viscosity, and hyponatremia may occur.

**Aseptic Meningitis Syndrome (AMS):** Aseptic meningitis syndrome (AMS) may occur, especially with high doses or rapid infusion. AMS usually begins within several hours to 2 days following ALYGLO treatment.

**Hemolysis:** Delayed hemolytic anemia due to enhanced red blood cell (RBC) sequestration and acute hemolysis consistent with intravascular hemolysis have been reported. Cases of severe hemolysis-related renal dysfunction/failure or disseminated intravascular coagulation have occurred following infusion of IGIV. Closely monitor patients for clinical signs and symptoms of hemolysis, particularly patients with risk factors.

**Transfusion-Related Acute Lung Injury:** Noncardiogenic pulmonary edema (transfusion-related acute lung injury [TRALI]) may occur. TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal left ventricular function, and fever. Patients with TRALI may be managed using oxygen therapy with adequate ventilator support. Monitor patients for pulmonary adverse reactions.

**Transmissible Infectious Agents:** Because ALYGLO is made from human blood, it may carry a risk of transmitting infectious agents (eg, viruses, the variant Creutzfeldt-Jakob disease [vCJD] agent and, theoretically, the Creutzfeldt-Jakob disease [CJD] agent).

**Interference with Laboratory Tests:** After infusion of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for a misleading interpretation.

**Adverse reactions** (observed in ≥ 5% of study subjects) were headache, nausea/vomiting, fatigue, nasal/sinus congestion, rash, arthralgia, diarrhea, muscle pain/aches, infusion site pain/swelling, abdominal pain/discomfort, cough, and dizziness.

It is recommended that ALYGLO be administered separately from other drugs or medications.

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